

Appl. No. : 10/072,537
Filed : February 8, 2002

AMENDMENTS TO THE CLAIMS

1. (Twice Amended) A nipple aspirate fluid aspiration device, comprising:
an adjustable support, defining a concavity, the support comprising a plurality of petals, movable throughout an adjustment range;
~~at least one three~~ inflatable bladders within the concavity; and
a vacuum source in communication with the concavity;
a heat source; and
a fluid circulation pathway for circulating a fluid through the bladders.
2. (Canceled)
3. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 1, wherein each petal carries an inflatable bladder.
4. (Cancelled)
5. (Currently amended) A nipple aspirate fluid aspiration device as in Claim 1[[4]], wherein the heat source is in thermally conductive contact with the bladder.
6. (Cancelled)
7. (Currently amended) A nipple aspirate fluid aspiration device as in Claim 1[[2]], wherein the heat source is in thermally conductive contact with the fluid so that the fluid heats the bladder.
8. (Cancelled)
9. (Original) A nipple aspirate fluid aspiration device as in Claim 1, further comprising a control for inflating and deflating the bladder in accordance with a predetermined program.
10. (Original) A nipple aspirate fluid aspiration device as in Claim 9 wherein the predetermined program comprises alternating inflation and deflation cycles.
11. (Original) A nipple aspirate fluid aspiration device as in Claim 10 wherein the predetermined program inflates the bladder within the range of from about 2 to about 40 cycles per minute.
12. (Original) A nipple aspirate fluid aspiration device as in Claim 11 wherein the predetermined program inflates the bladder within the range of from about 3 to about 12 cycles per minute.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

13. (Original) A nipple aspirate fluid aspiration device as in Claim 10 wherein the predetermined program maintains the bladder inflated within the range of from about 4 to about 8 seconds per cycle.

14. (Original) A nipple aspirate fluid aspiration device as in Claim 1, wherein the bladder is inflatable from a reduced profile along an axis transverse to the support and an inflated profile along the axis.

15. (Original) A nipple aspirate fluid aspiration device as in Claim 14, wherein the bladder has a maximum thickness in the inflated profile along the axis within the range of from about .2 inches to about 2.0 inches.

16. (Currently amended) A device for obtaining an intraductal fluid sample from a non lactating breast, comprising:

a frame;

at least three supports on the frame, having first sides for facing in the direction of a patient when in use[;], the supports moveable throughout an adjustment range;

a moveable wall positioned in between the supports and the patient when in use;
and

a disposable patient interface positioned between the movable wall and the patient, for contacting the patient when in use; and

a control, for controlling the adjustment.

17. (Canceled)

18. (Cancelled)

19. (Cancelled)

20. (Currently amended) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 1619, wherein the control comprises a rotatable ring.

21. (Currently amended) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 1618, wherein each support has a proximal end in the direction of the frame, and a distal end in the direction of the patient, and the distal ends form an annular distal limit which is moveable between a first, small diameter and a second, large diameter at the limits of the adjustment range.

Appl. No. : 10/072,537
Filed : February 8, 2002

22. (Original) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 21, wherein the first diameter is within the range of from about 2.5 inches to about 4.5 inches.

23. (Original) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 21, wherein the second diameter is within the range of from about 3.5 inches to about 6.5 inches.

24. (Previously presented) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 16, wherein the movable wall comprises a wall on an inflatable bladder.

25. (Currently amended) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 24, further comprising an inflatable bladder carried by each of the supports.

26. (Original) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 16, wherein the disposable patient interface comprises a flexible membrane.

27. (Original) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 26, wherein the flexible membrane comprises a tubular body having a proximal end with a first diameter and a distal end with a second, larger diameter.

28. (Original) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 27, further comprising a releasable connector on the proximal end.

29. (Original) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 26, wherein the flexible membrane comprises a low durometer thermoplastic elastomer.

30. (Original) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 16, further comprising a heat source in thermal communication with the movable wall.

31. (Canceled)

32. (Canceled).

33. (Canceled).

34. (Currently amended) A device for obtaining an intraductal fluid sample from a non lactating breast, comprising:

a frame;

Appl. No. : 10/072,537
Filed : February 8, 2002

at least one-three supports on the frame, having a-first sides for facing in the direction of a patient when in use;

a moveable wall positioned in between the support and the patient when in use; and

a disposable patient interface positioned between the movable wall and the patient, for contacting the patient when in use, the patient interface comprising a flexible membrane having a tubular body with a proximal end having a first diameter and a second end having a second, larger diameter, and a releasable connector on the proximal end;

wherein the movable wall comprises a wall on an inflatable bladder.

35. (Cancelled)

36. (Currently amended) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 3534, wherein the supports are moveable throughout an adjustment range.

37. (Previously presented) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 36, further comprising a control, for controlling the adjustment.

38. (Previously presented) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 37, wherein the control comprises a rotatable ring.

39. (Previously presented) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 36, wherein each support has a proximal end in the direction of the frame, and a distal end in the direction of the patient, and the distal ends form an annular distal limit which is moveable between a first, small diameter and a second, large diameter at the limits of the adjustment range.

40. (Previously presented) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 39, wherein the first diameter is within the range of from about 2.5 inches to about 4.5 inches.

41. (Previously presented) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 39, wherein the second diameter is within the range of from about 3.5 inches to about 6.5 inches.

42. (Cancelled)

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

43. (Currently amended) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 4234, comprising an inflatable bladder carried by each of the supports.

44. (Previously presented) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 34, wherein the flexible membrane comprises a low durometer thermoplastic elastomer.

45. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 1, further comprising:

- a control unit;
- a patient interface unit, carrying the adjustable support; and
- a control line extending between the control unit and the patient interface unit.

46. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 45, further comprising a closed fluid circulation loop, having a reservoir removably carried by the control unit in communication with the bladder carried by the patient interface unit.

47. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 46, wherein the bladder comprises at least 3 inflatable lobes.

48. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 47, comprising at least 6 inflatable lobes.

49. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 46, further comprising a heat exchange fluid contained within the closed loop.

50. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 47, wherein each lobe has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches.

51. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 50, wherein each lobe has an inflated width of no more than about 2 inches and an inflated length of no more than about 3 inches.

52. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 1, wherein the bladder has an inflated thickness of no more than about 1 inch.

53. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 52, wherein the bladder has an inflated thickness of no more than about 0.5 inches.

Appl. No. : 10/072,537
Filed : February 8, 2002

54. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 45, further comprising a heat source in the control unit.

55. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 46, further comprising a pump in the control unit.

56. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 55, wherein the fluid circulation loop is positioned such that the pump causes fluid circulation through the loop.

57. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 1, further comprising a disposable patient interface carried by the adjustable support, for contacting the patient.

58. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 57, wherein the disposable patient interface comprises a flexible polymeric membrane.

59. (Previously presented) A nipple aspirate fluid aspiration device as in Claim 58, wherein the disposable patient interface further comprises a rigid support for maintaining patency under vacuum, attached to the flexible polymeric membrane.

60. (Currently amended) A nipple aspirate fluid aspiration device as in Claim [[1]]59, wherein the rigid support proximal cap comprises at least a first retention structure for releasable connection with a complementary second retention structure on a handpiece.

61. (Currently amended) A nipple aspirate fluid aspiration device as in Claim [[1]]60, wherein the first retention structure comprises a recess on the rigid support proximal cap.

62. (Currently amended) A nipple aspirate fluid aspiration device as in Claim [[1]]60, wherein the first retention structure comprises a projection on the rigid support proximal cap.

63. (Currently amended) A nipple aspirate fluid aspiration device as in Claim 1, further comprising a central processing unit for controlling the inflatable bladders.

64. (Currently amended) A nipple aspirate fluid aspiration device as in Claim 45, further comprising a central processing unit for controlling the inflatable bladders.

65. (New) A nipple aspirate fluid aspiration device, comprising:
an adjustable support, defining a concavity, the support comprising a plurality of petals, movable throughout an adjustment range;
at least one inflatable bladder within the concavity;
a vacuum source in communication with the concavity; and

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

a control for inflating and deflating the bladder in accordance with a predetermined program;

wherein the predetermined program comprises alternating inflation and deflation cycles;

wherein the predetermined program inflates the bladder within the range of from about 3 to about 12 cycles per minute.

66. (New) A nipple aspirate fluid aspiration device as in Claim 65, wherein each petal carries an inflatable bladder.

67. (New) A nipple aspirate fluid aspiration device as in Claim 65, further comprising a heat source.

68. (New) A nipple aspirate fluid aspiration device as in Claim 67, wherein the heat source is in thermally conductive contact with the bladder.

69. (New) A nipple aspirate fluid aspiration device as in Claim 67, further comprising a fluid circulation pathway for circulating a fluid through the bladder.

70. (New) A nipple aspirate fluid aspiration device as in Claim 69, wherein the heat source is in thermally conductive contact with the fluid so that the fluid heats the bladder.

71. (New) A nipple aspirate fluid aspiration device as in Claim 69, further comprising at least three inflatable bladders, in fluid communication with the circulation pathway.

72. (New) A nipple aspirate fluid aspiration device as in Claim 65 wherein the predetermined program maintains the bladder inflated within the range of from about 4 to about 8 seconds per cycle.

73. (New) A nipple aspirate fluid aspiration device as in Claim 65, wherein the bladder is inflatable from a reduced profile along an axis transverse to the support and an inflated profile along the axis.

74. (New) A nipple aspirate fluid aspiration device as in Claim 67, wherein the bladder has a maximum thickness in the inflated profile along the axis within the range of from about .2 inches to about 2.0 inches.

75. (New) A nipple aspirate fluid aspiration device as in Claim 65, further comprising:

a control unit;

a patient interface unit, carrying the adjustable support; and

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

a control line extending between the control unit and the patient interface unit.

76. (New) A nipple aspirate fluid aspiration device as in Claim 75, further comprising a closed fluid circulation loop, having a reservoir removably carried by the control unit in communication with the bladder carried by the patient interface unit.

77. (New) A nipple aspirate fluid aspiration device as in Claim 76, wherein the bladder comprises at least 3 inflatable lobes.

78. (New) A nipple aspirate fluid aspiration device as in Claim 77, comprising at least 6 inflatable lobes.

79. (New) A nipple aspirate fluid aspiration device as in Claim 76, further comprising a heat exchange fluid contained within the closed loop.

80. (New) A nipple aspirate fluid aspiration device as in Claim 77, wherein each lobe has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches.

81. (New) A nipple aspirate fluid aspiration device as in Claim 80, wherein each lobe has an inflated width of no more than about 2 inches and an inflated length of no more than about 3 inches.

82. (New) A nipple aspirate fluid aspiration device as in Claim 65, wherein the bladder has an inflated thickness of no more than about 1 inch.

83. (New) A nipple aspirate fluid aspiration device as in Claim 82, wherein the bladder has an inflated thickness of no more than about 0.5 inches.

84. (New) A nipple aspirate fluid aspiration device as in Claim 75, further comprising a heat source in the control unit.

85. (New) A nipple aspirate fluid aspiration device as in Claim 76, further comprising a pump in the control unit.

86. (New) A nipple aspirate fluid aspiration device as in Claim 85, wherein the fluid circulation loop is positioned such that the pump causes fluid circulation through the loop.

87. (New) A nipple aspirate fluid aspiration device as in Claim 65, further comprising a disposable patient interface carried by the adjustable support, for contacting the patient.

88. (New) A nipple aspirate fluid aspiration device as in Claim 87, wherein the disposable patient interface comprises a flexible polymeric membrane.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

89. (New) A nipple aspirate fluid aspiration device as in Claim 88, wherein the disposable patient interface further comprises a rigid support for maintaining patency under vacuum, attached to the flexible polymeric membrane.

90. (New) A nipple aspirate fluid aspiration device as in Claim 89, wherein the rigid support comprises a proximal cap, the proximal cap comprising at least a first retention structure for releasable connection with a complementary second retention structure on a handpiece.

91. (New) A nipple aspirate fluid aspiration device as in Claim 90, wherein the first retention structure comprises a recess on the proximal cap.

92. (New) A nipple aspirate fluid aspiration device as in Claim 90, wherein the first retention structure comprises a projection on the proximal cap.

93. (New) A nipple aspirate fluid aspiration device as in Claim 65, further comprising a central processing unit for controlling the inflatable bladder.

94. (New) A nipple aspirate fluid aspiration device as in Claim 75, further comprising a central processing unit for controlling the inflatable bladder.

95. (New) A nipple aspirate fluid aspiration device, comprising:
an adjustable support, defining a concavity, the support comprising a plurality of petals, movable throughout an adjustment range;
at least one inflatable bladder within the concavity; and
a vacuum source in communication with the concavity;
wherein the bladder is inflatable from a reduced profile along an axis transverse to the support and an inflated profile along the axis.

96. (New) A nipple aspirate fluid aspiration device as in Claim 95, wherein each petal carries an inflatable bladder.

97. (New) A nipple aspirate fluid aspiration device as in Claim 95, further comprising a heat source.

98. (New) A nipple aspirate fluid aspiration device as in Claim 97, wherein the heat source is in thermally conductive contact with the bladder.

99. (New) A nipple aspirate fluid aspiration device as in Claim 97, further comprising a fluid circulation pathway for circulating a fluid through the bladder.

100. (New) A nipple aspirate fluid aspiration device as in Claim 99, wherein the heat source is in thermally conductive contact with the fluid so that the fluid heats the bladder.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

101. (New) A nipple aspirate fluid aspiration device as in Claim 99, further comprising at least three inflatable bladders, in fluid communication with the circulation pathway.

102. (New) A nipple aspirate fluid aspiration device as in Claim 95, further comprising a control for inflating and deflating the bladder in accordance with a predetermined program.

103. (New) A nipple aspirate fluid aspiration device as in Claim 102 wherein the predetermined program comprises alternating inflation and deflation cycles.

104. (New) A nipple aspirate fluid aspiration device as in Claim 103 wherein the predetermined program inflates the bladder within the range of from about 2 to about 40 cycles per minute.

105. (New) A nipple aspirate fluid aspiration device as in Claim 104 wherein the predetermined program inflates the bladder within the range of from about 3 to about 12 cycles per minute.

106. (New) A nipple aspirate fluid aspiration device as in Claim 103 wherein the predetermined program maintains the bladder inflated within the range of from about 4 to about 8 seconds per cycle.

107. (New) A nipple aspirate fluid aspiration device as in Claim 95, wherein the bladder has a maximum thickness in the inflated profile along the axis within the range of from about .2 inches to about 2.0 inches.

108. (New) A nipple aspirate fluid aspiration device as in Claim 95, further comprising:

- a control unit;
- a patient interface unit, carrying the adjustable support; and
- a control line extending between the control unit and the patient interface unit.

109. (New) A nipple aspirate fluid aspiration device as in Claim 108, further comprising a closed fluid circulation loop, having a reservoir removably carried by the control unit in communication with the bladder carried by the patient interface unit.

110. (New) A nipple aspirate fluid aspiration device as in Claim 109, wherein the bladder comprises at least 3 inflatable lobes.

111. (New) A nipple aspirate fluid aspiration device as in Claim 110, comprising at least 6 inflatable lobes.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

112. (New) A nipple aspirate fluid aspiration device as in Claim 109, further comprising a heat exchange fluid contained within the closed loop.

113. (New) A nipple aspirate fluid aspiration device as in Claim 110, wherein each lobe has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches.

114. (New) A nipple aspirate fluid aspiration device as in Claim 113, wherein each lobe has an inflated width of no more than about 2 inches and an inflated length of no more than about 3 inches.

115. (New) A nipple aspirate fluid aspiration device as in Claim 95, wherein the bladder has an inflated thickness of no more than about 1 inch.

116. (New) A nipple aspirate fluid aspiration device as in Claim 115, wherein the bladder has an inflated thickness of no more than about 0.5 inches.

117. (New) A nipple aspirate fluid aspiration device as in Claim 108, further comprising a heat source in the control unit.

118. (New) A nipple aspirate fluid aspiration device as in Claim 109, further comprising a pump in the control unit.

119. (New) A nipple aspirate fluid aspiration device as in Claim 118, wherein the fluid circulation loop is positioned such that the pump causes fluid circulation through the loop.

120. (New) A nipple aspirate fluid aspiration device as in Claim 95, further comprising a disposable patient interface carried by the adjustable support, for contacting the patient.

121. (New) A nipple aspirate fluid aspiration device as in Claim 120, wherein the disposable patient interface comprises a flexible polymeric membrane.

122. (New) A nipple aspirate fluid aspiration device as in Claim 121, wherein the disposable patient interface further comprises a rigid support for maintaining patency under vacuum, attached to the flexible polymeric membrane.

123. (New) A nipple aspirate fluid aspiration device as in Claim 122, wherein the rigid support comprises a proximal cap, having at least a first retention structure for releasable connection with a complementary second retention structure on a handpiece.

124. (New) A nipple aspirate fluid aspiration device as in Claim 123, wherein the first retention structure comprises a recess on the proximal cap.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

125. (New) A nipple aspirate fluid aspiration device as in Claim 123, wherein the first retention structure comprises a projection on the proximal cap.

126. (New) A nipple aspirate fluid aspiration device as in Claim 95, further comprising a central processing unit for controlling the inflatable bladder.

127. (New) A nipple aspirate fluid aspiration device as in Claim 108, further comprising a central processing unit for controlling the inflatable bladder.

128. (New) A device for obtaining an intraductal fluid sample from a non lactating breast, comprising:

a frame;

at least three supports on the frame, having first sides for facing in the direction of a patient when in use;

a moveable wall positioned in between the supports and the patient when in use; and

a disposable patient interface positioned between the movable wall and the patient, for contacting the patient when in use;

wherein the supports are moveable throughout an adjustment range; and

wherein each support has a proximal end in the direction of the frame, and a distal end in the direction of the patient, and the distal ends form an annular distal limit which is moveable between a first, small diameter and a second, large diameter at the limits of the adjustment range.

129. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 128, further comprising a control, for controlling the adjustment.

130. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 129, wherein the control comprises a rotatable ring.

131. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 128, wherein the first diameter is within the range of from about 2.5 inches to about 4.5 inches.

132. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 128, wherein the second diameter is within the range of from about 3.5 inches to about 6.5 inches.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

133. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 128, wherein the movable wall comprises a wall on an inflatable bladder.

134. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 133, comprising an inflatable bladder carried by each of the supports.

135. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 128, wherein the disposable patient interface comprises a flexible membrane.

136. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 135, wherein the flexible membrane comprises a tubular body having a proximal end with a first diameter and a distal end with a second, larger diameter.

137. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 136, further comprising a releasable connector on the proximal end.

138. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 135, wherein the flexible membrane comprises a low durometer thermoplastic elastomer.

139. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 128, further comprising a heat source in thermal communication with the movable wall.

140. (New) A device for obtaining an intraductal fluid sample from a non lactating breast, comprising:

a frame;

at least three supports on the frame, having first sides for facing in the direction of a patient when in use;

a moveable wall positioned in between the supports and the patient when in use; and

a disposable patient interface positioned between the movable wall and the patient, for contacting the patient when in use;

wherein the movable wall comprises a wall on an inflatable bladder.

141. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 140, wherein the supports are moveable throughout an adjustment range.

142. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 141, further comprising a control, for controlling the adjustment.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

143. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 142, wherein the control comprises a rotatable ring.

144. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 141, wherein each support has a proximal end in the direction of the frame, and a distal end in the direction of the patient, and the distal ends form an annular distal limit which is moveable between a first, small diameter and a second, large diameter at the limits of the adjustment range.

145. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 144, wherein the first diameter is within the range of from about 2.5 inches to about 4.5 inches.

146. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 144, wherein the second diameter is within the range of from about 3.5 inches to about 6.5 inches.

147. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 140, further comprising an inflatable bladder carried by each of the supports.

148. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 140, wherein the disposable patient interface comprises a flexible membrane.

149. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 148, wherein the flexible membrane comprises a tubular body having a proximal end with a first diameter and a distal end with a second, larger diameter.

150. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 149, further comprising a releasable connector on the proximal end.

151. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 148, wherein the flexible membrane comprises a low durometer thermoplastic elastomer.

152. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 140, further comprising a heat source in thermal communication with the movable wall.

153. (New) A device for obtaining an intraductal fluid sample from a non lactating breast, comprising:

a frame;

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

at least three supports on the frame, having first sides for facing in the direction of a patient when in use;

a moveable wall positioned in between the supports and the patient when in use; and

a disposable patient interface positioned between the movable wall and the patient, for contacting the patient when in use;

wherein the disposable patient interface comprises a flexible membrane; and

wherein the flexible membrane comprises a tubular body having a proximal end with a first diameter and a distal end with a second, larger diameter.

154. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 153, wherein the supports are moveable throughout an adjustment range.

155. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 154, further comprising a control, for controlling the adjustment.

156. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 155, wherein the control comprises a rotatable ring.

157. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 154, wherein each support has a proximal end in the direction of the frame, and a distal end in the direction of the patient, and the distal ends form an annular distal limit which is moveable between a first, small diameter and a second, large diameter at the limits of the adjustment range.

158. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 157, wherein the first diameter is within the range of from about 2.5 inches to about 4.5 inches.

159. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 157, wherein the second diameter is within the range of from about 3.5 inches to about 6.5 inches.

160. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 153, wherein the movable wall comprises a wall on an inflatable bladder.

161. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 160, further comprising an inflatable bladder carried by each of the supports.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

162. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 153, further comprising a releasable connector on the proximal end.

163. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 153, wherein the flexible membrane comprises a low durometer thermoplastic elastomer.

164. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in claim 153, further comprising a heat source in thermal communication with the movable wall.

165. (New) A device for obtaining an intraductal fluid sample from a non lactating breast, comprising:

a frame;

at least three supports on the frame, having first sides for facing in the direction of a patient when in use, the supports moveable throughout an adjustment range;

a moveable wall positioned in between the supports and the patient when in use;

a disposable patient interface positioned between the movable wall and the patient, for contacting the patient when in use, the patient interface comprising a flexible membrane having a tubular body with a proximal end having a first diameter and a second end having a second, larger diameter, and a releasable connector on the proximal end; and

a control, for controlling the adjustment.

166. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 165, wherein the control comprises a rotatable ring.

167. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 165, wherein each support has a proximal end in the direction of the frame, and a distal end in the direction of the patient, and the distal ends form an annular distal limit which is moveable between a first, small diameter and a second, large diameter at the limits of the adjustment range.

168. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 167, wherein the first diameter is within the range of from about 2.5 inches to about 4.5 inches.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

169. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 167, wherein the second diameter is within the range of from about 3.5 inches to about 6.5 inches.

170. (New) A device for obtaining an intraductal fluid sample from a non-lactating breast as in Claim 165, wherein the movable wall comprises a wall on an inflatable bladder.

171. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 170, comprising an inflatable bladder carried by each of the supports.

172. (New) A device for obtaining an intraductal fluid sample from a non lactating breast as in Claim 165, wherein the flexible membrane comprises a low durometer thermoplastic elastomer.

173. (New) A nipple aspirate fluid aspiration device, comprising:
an adjustable support, defining a concavity, the support comprising a plurality of petals, movable throughout an adjustment range;
at least one inflatable bladder within the concavity;
a vacuum source in communication with the concavity;
a control unit;
a patient interface unit, carrying the adjustable support; and
a control line extending between the control unit and the patient interface unit.

174. (New) A nipple aspirate fluid aspiration device as in Claim 173, wherein each petal carries an inflatable bladder.

175. (New) A nipple aspirate fluid aspiration device as in Claim 173, further comprising a heat source.

176. (New) A nipple aspirate fluid aspiration device as in Claim 175, wherein the heat source is in thermally conductive contact with the bladder.

177. (New) A nipple aspirate fluid aspiration device as in Claim 175, further comprising a fluid circulation pathway for circulating a fluid through the bladder.

178. (New) A nipple aspirate fluid aspiration device as in Claim 177, wherein the heat source is in thermally conductive contact with the fluid so that the fluid heats the bladder.

179. (New) A nipple aspirate fluid aspiration device as in Claim 177, further comprising at least three inflatable bladders, in fluid communication with the circulation pathway.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

180. (New) A nipple aspirate fluid aspiration device as in Claim 173, wherein the control unit controls inflating and deflating the bladder in accordance with a predetermined program.

181. (New) A nipple aspirate fluid aspiration device as in Claim 180, wherein the predetermined program comprises alternating inflation and deflation cycles.

182. (New) A nipple aspirate fluid aspiration device as in Claim 181, wherein the predetermined program inflates the bladder within the range of from about 2 to about 40 cycles per minute.

183. (New) A nipple aspirate fluid aspiration device as in Claim 182, wherein the predetermined program inflates the bladder within the range of from about 3 to about 12 cycles per minute.

184. (New) A nipple aspirate fluid aspiration device as in Claim 181, wherein the predetermined program maintains the bladder inflated within the range of from about 4 to about 8 seconds per cycle.

185. (New) A nipple aspirate fluid aspiration device as in Claim 173, wherein the bladder is inflatable from a reduced profile along an axis transverse to the support and an inflated profile along the axis.

186. (New) A nipple aspirate fluid aspiration device as in Claim 185, wherein the bladder has a maximum thickness in the inflated profile along the axis within the range of from about .2 inches to about 2.0 inches.

187. (New) A nipple aspirate fluid aspiration device as in Claim 173, further comprising a closed fluid circulation loop, having a reservoir removably carried by the control unit in communication with the bladder carried by the patient interface unit.

188. (New) A nipple aspirate fluid aspiration device as in Claim 187, wherein the bladder comprises at least 3 inflatable lobes.

189. (New) A nipple aspirate fluid aspiration device as in Claim 188, comprising at least 6 inflatable lobes.

190. (New) A nipple aspirate fluid aspiration device as in Claim 187, further comprising a heat exchange fluid contained within the closed loop.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

191. (New) A nipple aspirate fluid aspiration device as in Claim 188, wherein each lobe has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches.

192. (New) A nipple aspirate fluid aspiration device as in Claim 191, wherein each lobe has an inflated width of no more than about 2 inches and an inflated length of no more than about 3 inches.

193. (New) A nipple aspirate fluid aspiration device as in Claim 173, wherein the bladder has an inflated thickness of no more than about 1 inch.

194. (New) A nipple aspirate fluid aspiration device as in Claim 193, wherein the bladder has an inflated thickness of no more than about 0.5 inches.

195. (New) A nipple aspirate fluid aspiration device as in Claim 173, further comprising a heat source in the control unit.

196. (New) A nipple aspirate fluid aspiration device as in Claim 187, further comprising a pump in the control unit.

197. (New) A nipple aspirate fluid aspiration device as in Claim 196, wherein the fluid circulation loop is positioned such that the pump causes fluid circulation through the loop.

198. (New) A nipple aspirate fluid aspiration device as in Claim 173, further comprising a disposable patient interface carried by the adjustable support, for contacting the patient.

199. (New) A nipple aspirate fluid aspiration device as in Claim 198, wherein the disposable patient interface comprises a flexible polymeric membrane.

200. (New) A nipple aspirate fluid aspiration device as in Claim 199, wherein the disposable patient interface further comprises a rigid support for maintaining patency under vacuum, attached to the flexible polymeric membrane.

201. (New) A nipple aspirate fluid aspiration device as in Claim 200, wherein the rigid support comprises a proximal cap, wherein the proximal cap comprises at least a first retention structure for releasable connection with a complementary second retention structure on a handpiece.

202. (New) A nipple aspirate fluid aspiration device as in Claim 201, wherein the first retention structure comprises a recess on the proximal cap.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

203. (New) A nipple aspirate fluid aspiration device as in Claim 201, wherein the first retention structure comprises a projection on the proximal cap.

204. (New) A nipple aspirate fluid aspiration device as in Claim 187, further comprising a central processing unit for controlling the inflatable bladder.

205. (New) A nipple aspirate fluid aspiration device as in Claim 187, further comprising a central processing unit for controlling the inflatable bladder.

206. (New) A nipple aspirate fluid aspiration device, comprising:
an adjustable support, defining a concavity, the support comprising a plurality of petals, movable throughout an adjustment range;
at least one inflatable bladder within the concavity;
a vacuum source in communication with the concavity; and
a disposable patient interface carried by the adjustable support, for contacting the patient;
wherein the disposable patient interface comprises a flexible polymeric membrane.

207. (New) A nipple aspirate fluid aspiration device as in Claim 206, wherein each petal carries an inflatable bladder.

208. (New) A nipple aspirate fluid aspiration device as in Claim 206, further comprising a heat source.

209. (New) A nipple aspirate fluid aspiration device as in Claim 208, wherein the heat source is in thermally conductive contact with the bladder.

210. (New) A nipple aspirate fluid aspiration device as in Claim 208, further comprising a fluid circulation pathway for circulating a fluid through the bladder.

211. (New) A nipple aspirate fluid aspiration device as in Claim 210, wherein the heat source is in thermally conductive contact with the fluid so that the fluid heats the bladder.

212. (New) A nipple aspirate fluid aspiration device as in Claim 210, further comprising at least three inflatable bladders, in fluid communication with the circulation pathway.

213. (New) A nipple aspirate fluid aspiration device as in Claim 206, further comprising a control for inflating and deflating the bladder in accordance with a predetermined program.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

214. (New) A nipple aspirate fluid aspiration device as in Claim 213, wherein the predetermined program comprises alternating inflation and deflation cycles.

215. (New) A nipple aspirate fluid aspiration device as in Claim 214, wherein the predetermined program inflates the bladder within the range of from about 2 to about 40 cycles per minute.

216. (New) A nipple aspirate fluid aspiration device as in Claim 215, wherein the predetermined program inflates the bladder within the range of from about 3 to about 12 cycles per minute.

217. (New) A nipple aspirate fluid aspiration device as in Claim 214, wherein the predetermined program maintains the bladder inflated within the range of from about 4 to about 8 seconds per cycle.

218. (New) A nipple aspirate fluid aspiration device as in Claim 206, wherein the bladder is inflatable from a reduced profile along an axis transverse to the support and an inflated profile along the axis.

219. (New) A nipple aspirate fluid aspiration device as in Claim 218, wherein the bladder has a maximum thickness in the inflated profile along the axis within the range of from about .2 inches to about 2.0 inches.

220. (New) A nipple aspirate fluid aspiration device as in Claim 206, further comprising:

- a control unit;
- a patient interface unit, carrying the adjustable support; and
- a control line extending between the control unit and the patient interface unit.

221. (New) A nipple aspirate fluid aspiration device as in Claim 220, further comprising a closed fluid circulation loop, having a reservoir removably carried by the control unit in communication with the bladder carried by the patient interface unit.

222. (New) A nipple aspirate fluid aspiration device as in Claim 221, wherein the bladder comprises at least 3 inflatable lobes.

223. (New) A nipple aspirate fluid aspiration device as in Claim 222, comprising at least 6 inflatable lobes.

224. (New) A nipple aspirate fluid aspiration device as in Claim 221, further comprising a heat exchange fluid contained within the closed loop.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

225. (New) A nipple aspirate fluid aspiration device as in Claim 222, wherein each lobe has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches.

226. (New) A nipple aspirate fluid aspiration device as in Claim 225, wherein each lobe has an inflated width of no more than about 2 inches and an inflated length of no more than about 3 inches.

227. (New) A nipple aspirate fluid aspiration device as in Claim 206, wherein the bladder has an inflated thickness of no more than about 1 inch.

228. (New) A nipple aspirate fluid aspiration device as in Claim 227, wherein the bladder has an inflated thickness of no more than about 0.5 inches.

229. (New) A nipple aspirate fluid aspiration device as in Claim 220, further comprising a heat source in the control unit.

230. (New) A nipple aspirate fluid aspiration device as in Claim 221, further comprising a pump in the control unit.

231. (New) A nipple aspirate fluid aspiration device as in Claim 230, wherein the fluid circulation loop is positioned such that the pump causes fluid circulation through the loop.

232. (New) A nipple aspirate fluid aspiration device as in Claim 206, wherein the disposable patient interface further comprises a rigid support for maintaining patency under vacuum, attached to the flexible polymeric membrane.

233. (New) A nipple aspirate fluid aspiration device as in Claim 206, further comprising a proximal cap on the disposable patient interface, wherein the proximal cap comprises at least a first retention structure for releasable connection with a complementary second retention structure on a handpiece.

234. (New) A nipple aspirate fluid aspiration device as in Claim 233, wherein the first retention structure comprises a recess on the proximal cap.

235. (New) A nipple aspirate fluid aspiration device as in Claim 233, wherein the first retention structure comprises a projection on the proximal cap.

236. (New) A nipple aspirate fluid aspiration device as in Claim 206, further comprising a central processing unit for controlling the inflatable bladder.

237. (New) A nipple aspirate fluid aspiration device as in Claim 220, further comprising a central processing unit for controlling the inflatable bladder.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

238. (New) A nipple aspirate fluid aspiration device, comprising:
an adjustable support, defining a concavity, the support comprising a plurality of
petals, movable throughout an adjustment range;
at least one inflatable bladder within the concavity;
a vacuum source in communication with the concavity; and
a disposable patient interface having a proximal cap, wherein the proximal cap
comprises at least a first retention structure for releasable connection with a
complementary second retention structure on a handpiece.

239. (New) A nipple aspirate fluid aspiration device as in Claim 238, wherein each
petal carries an inflatable bladder.

240. (New) A nipple aspirate fluid aspiration device as in Claim 238, further
comprising a heat source.

241. (New) A nipple aspirate fluid aspiration device as in Claim 240, wherein the heat
source is in thermally conductive contact with the bladder.

242. (New) A nipple aspirate fluid aspiration device as in Claim 240, further
comprising a fluid circulation pathway for circulating a fluid through the bladder.

243. (New) A nipple aspirate fluid aspiration device as in Claim 242, wherein the heat
source is in thermally conductive contact with the fluid so that the fluid heats the bladder.

244. (New) A nipple aspirate fluid aspiration device as in Claim 242, further
comprising at least three inflatable bladders, in fluid communication with the circulation
pathway.

245. (New) A nipple aspirate fluid aspiration device as in Claim 238, further
comprising a control for inflating and deflating the bladder in accordance with a predetermined
program.

246. (New) A nipple aspirate fluid aspiration device as in Claim 245, wherein the
predetermined program comprises alternating inflation and deflation cycles.

247. (New) A nipple aspirate fluid aspiration device as in Claim 246, wherein the
predetermined program inflates the bladder within the range of from about 2 to about 40 cycles
per minute.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

248. (New) A nipple aspirate fluid aspiration device as in Claim 247, wherein the predetermined program inflates the bladder within the range of from about 3 to about 12 cycles per minute.

249. (New) A nipple aspirate fluid aspiration device as in Claim 246, wherein the predetermined program maintains the bladder inflated within the range of from about 4 to about 8 seconds per cycle.

250. (New) A nipple aspirate fluid aspiration device as in Claim 238, wherein the bladder is inflatable from a reduced profile along an axis transverse to the support and an inflated profile along the axis.

251. (New) A nipple aspirate fluid aspiration device as in Claim 250, wherein the bladder has a maximum thickness in the inflated profile along the axis within the range of from about .2 inches to about 2.0 inches.

252. (New) A nipple aspirate fluid aspiration device as in Claim 238, further comprising:

a control unit;
a patient interface unit, carrying the adjustable support; and
a control line extending between the control unit and the patient interface unit.

253. (New) A nipple aspirate fluid aspiration device as in Claim 252, further comprising a closed fluid circulation loop, having a reservoir removably carried by the control unit in communication with the bladder carried by the patient interface unit.

254. (New) A nipple aspirate fluid aspiration device as in Claim 253, wherein the bladder comprises at least 3 inflatable lobes.

255. (New) A nipple aspirate fluid aspiration device as in Claim 254, comprising at least 6 inflatable lobes.

256. (New) A nipple aspirate fluid aspiration device as in Claim 253, further comprising a heat exchange fluid contained within the closed loop.

257. (New) A nipple aspirate fluid aspiration device as in Claim 254, wherein each lobe has an inflated width of no more than about 3 inches and an inflated length of no more than about 4 inches.

Appl. No. : **10/072,537**
Filed : **February 8, 2002**

258. (New) A nipple aspirate fluid aspiration device as in Claim 257, wherein each lobe has an inflated width of no more than about 2 inches and an inflated length of no more than about 3 inches.

259. (New) A nipple aspirate fluid aspiration device as in Claim 238, wherein the bladder has an inflated thickness of no more than about 1 inch.

260. (New) A nipple aspirate fluid aspiration device as in Claim 259, wherein the bladder has an inflated thickness of no more than about 0.5 inches.

261. (New) A nipple aspirate fluid aspiration device as in Claim 252, further comprising a heat source in the control unit.

262. (New) A nipple aspirate fluid aspiration device as in Claim 253, further comprising a pump in the control unit.

263. (New) A nipple aspirate fluid aspiration device as in Claim 262, wherein the fluid circulation loop is positioned such that the pump causes fluid circulation through the loop.

264. (New) A nipple aspirate fluid aspiration device as in Claim 238, wherein the disposable patient interface is carried by the adjustable support, for contacting the patient.

265. (New) A nipple aspirate fluid aspiration device as in Claim 264, wherein the disposable patient interface comprises a flexible polymeric membrane.

266. (New) A nipple aspirate fluid aspiration device as in Claim 238, wherein the first retention structure comprises a recess on the proximal cap.

267. (New) A nipple aspirate fluid aspiration device as in Claim 238, wherein the first retention structure comprises a projection on the proximal cap.

268. (New) A nipple aspirate fluid aspiration device as in Claim 238, further comprising a central processing unit for controlling the inflatable bladder.

269. (New) A nipple aspirate fluid aspiration device as in Claim 252, further comprising a central processing unit for controlling the inflatable bladder.